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What are the six degree-of-freedom errors of a robotically-machined femoral cavity in total hip arthroplasty and are they clinically important? An in-vitro study

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ABSTRACT

Errors during a robot-assisted THA may result in a femoral cavity with position and orientation different than planned. This can lead to a femoral component placement that inaccurately sets a patient's femoral anteversion (FA), femoral offset (FO), and vertical offset (VO). The objectives of this study were to determine the position and orientation errors of robotically-machined femoral cavities in six degrees of freedom and to determine how position and orientation errors translate into errors in the setting of FA, FO, and VO. After creating preoperative plans, robot-assisted THAs were performed on twelve cadaveric specimens. The position and orientation of the machined cavities were compared to those of the planned cavities to determine the errors in six degrees of freedom. Placement of femoral components into the machined cavities was simulated, and the differences in FA, FO, and VO between the simulated and planned component placement were computed. While bias (i.e. mean error) occurred for three of six degrees of freedom in femoral cavities machined by a robotic system, the root mean squared errors (RMSEs) when the placement of femoral component was simulated were limited to 1.9° for FA, 1.0 mm for FO, and 2.1 mm for VO and were clinically unimportant.

1. Introduction

Machining a femoral cavity with position and orientation accurate to the planned cavity is important in robot-assisted total hip arthroplasty (THA). Fixation of cementless femoral components is initially achieved with a press fit, and therefore the position and orientation of the machined cavity dictates the placement of the femoral component. Errors in the position and/or orientation of the machined cavity translate to error in femoral component placement. In which case, the patient's femoral anteversion (FA), femoral offset (FO), and vertical offset (VO) may not be set according to the preoperative plan and may subsequently result in adverse outcomes such as limited range of motion, poor abductor muscle strength, limp, and leg length inequality [1–13].

Various sources of inaccuracy can lead a robotic system to machine a cavity with different position and orientation than planned. Accuracy of surface-based registration can be influenced by the protocol of the preoperative CT scan, the surface model created in the planning software, and the bony points collected on the surface of a patient's femur for registration [14]. Errors in one or more of these sources can cause a robotic system to machine a cavity at the wrong location in a patient's femur.

While an extensive number of studies has been published on robot-assisted THA, only one study reported position and orientation errors of robotically-machined femoral cavities in six degrees of freedom [15]. However, the study tested an older generation of robotic systems which used pin-based registration to register the patient's anatomy to the preoperative plan, had a different robotic arm, and embodied other hardware components. The study also did not analyze how these errors propagate into errors in clinical variables of FA, FO, and VO which makes determining the clinical acceptability of the robot-assisted THA difficult. Currently, no study has simultaneously investigated the accuracy of a robotic system in executing a preoperative plan and its impact on FA, FO, and VO. Accordingly, an objective of this study was to quantify the bias (i.e. mean error) and precision (i.e. standard deviation of the error), according to ASTM standard E177-14, of the position and orientation errors in six degrees of freedom of femoral cavities machined by a state-of-the-art robotic system using surface-based registration. A second objective was to quantify how these errors

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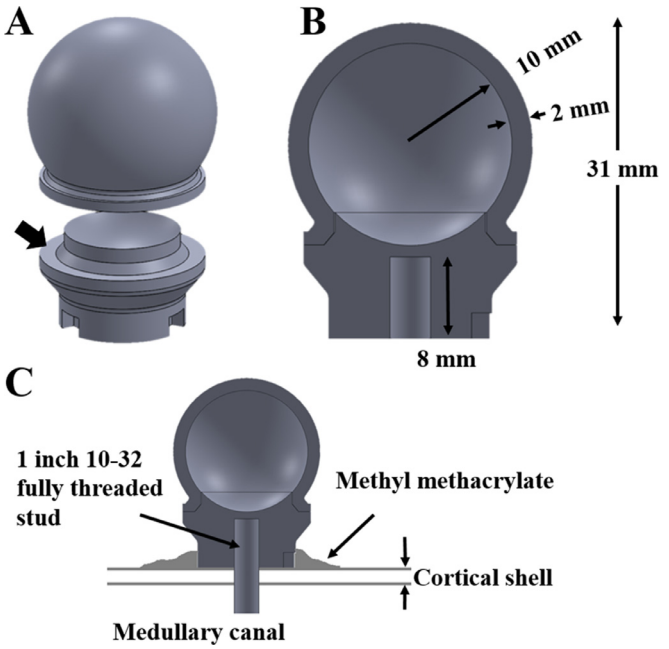

Fig. 1. Rendering of a fiducial marker. (A) A fiducial marker was designed in two parts: a cap and a body. The cap and body were assembled with cyanoacrylate applied to the flat rim (shown by arrow) around the body. (B) The cap and body when assembled formed a hollow sphere. The hollow sphere could be seen easily in CT images and with good contrast. (C) The fiducial marker was fixed to the surface of the bone by a threaded stud. The marker-bone junction was further secured by applying a small amount of methyl methacrylate. Choice of number of markers attached was made based on surface area available on the limb's femur. Markers were not attached in the region of the distal metaphysis or in the region proximal to the lesser trochanter. Each marker was attached by making incisions on the anterior side of the cadaveric limb to expose the femur, separating soft tissues adhering to the femur with a scalpel, drilling and tapping a hole at selected locations on the femoral shaft, threading the markers in place, and securing the junctions with methyl methacrylate. The incisions were closed with sutures after all markers were attached. Soft tissues were not removed to avoid difference in the quality of CT images collected for the present study and the quality of CT images collected for patients.

propagate into bias and precision of setting FA, FO, and VO after simulating placement of femoral components into these cavities and determine whether the errors in these variables are clinically important.

2. Methods

Twelve fresh-frozen cadaveric lower limbs were included for this study. Potential donors were screened with an anterior–posterior (AP) radiograph at the hip and knee. Limbs were excluded when radiographs showed existing hip or knee implants. Limbs that passed were subsequently scanned with a dual energy X-ray absorptiometry (DEXA) machine. Limbs with a t-score below −2.5 were excluded because lower scores indicate osteoporosis, a contraindication for the active robot used in this study. The average age was 76 years (range = 51–94 years), the average BMI was 24 (range = 16–34), four limbs were from male donors, and all limbs were from Caucasian donors.

Each limb was prepared for the robotic procedure with the following steps. First, seven to ten custom fiducial markers were attached along the femoral shaft (Fig. 1). Second, three sets of preoperative CT images were acquired. The first and second sets of images were generated from scanning with a high resolution protocol. Scanning was performed using a 16-slice CT scanner (GE Lightspeed 16, GE Healthcare, Chicago, IL) with 120 kV, 350–400 mA, and a large field of view. Images were reconstructed from the scan data with a slice thickness of 0.625 mm using two different reconstruction filters—the BONE reconstruction filter and the STANDARD reconstruction filter. The third set of images was generated by retrospectively reconstructing the raw data in the scanner such that the images have identical slice thickness and are of regions indicated in the imaging protocol recommended by the manufacturer of the robotic system. Images of the proximal femur to the isthmus and the distal condyles were reconstructed with 1.25 mm slice thickness and using the STANDARD reconstruction filter. Each set of images was used for a different purpose (Fig. 2).

Third, limbs were disarticulated at the knee, and soft tissues were removed leaving only the femur and attached fiducial markers; soft tissues were removed to facilitate fixation of the femur to the robot. Afterward, preoperative planning was performed on a planning workstation (TPLAN®, Think Surgical, Inc.). The same brand of collarless femoral component (ML Taper, Zimmer-Biomet, Inc.) was used for all cases. Size, positioning, and configuration of the femoral component were adjusted until four criteria were met (Fig. 3). The completed plan included a transformation matrix ($T_{CAD \rightarrow preop}$) for transforming the CAD model of the planned femoral component with the selected component head (CAD component model) from the local coordinate system of the CAD model (CAD coordinate system) to the planned placement in the CT-based coordinate system (preoperative CT-based coordinate system) (Fig. 2). $T_{CAD \rightarrow preop}$ also transformed the CAD model of the planned cavity (CAD cavity model) to the planned position and orientation because the CAD cavity model had the same coordinate system as the CAD component model.

Next, the femoral cavity was machined using an active robotic system (TCAT®, Think Surgical, Inc.). Each femur was clamped at two locations (Fig. 4A and B) and the two clamps were fixed to the front of the robot. This method of fixation differs from the clinical method in which a patient's lower limb is secured in a holder, and pins, screwed into the femoral head, are used to fix the patient's femur to the robot. The femur was positioned with the posterior side up. A probe mounted at the front of the robot (Fig. 4C) was used to digitize points on the surface of the bone following instructions displayed on a monitor. Machining was performed autonomously by the robot. Potable tap water was used for irrigation.

Lastly, two sets of postoperative CT images were acquired. The same 16-slice CT scanner (GE Lightspeed 16) used for preoperative imaging was used. Scanning was performed with 120 kV, automatic mA with noise index set to 0.5, and a small field of view. Two sets of images were reconstructed from the scan data with a slice thickness of 0.625 mm using the BONE reconstruction filter and the STANDARD reconstruction filter.

Four 3D models were created for each specimen using Mimics® (Materialise, Germany) from the CT images (Fig. 2). Two 3D models of fiducial markers (preoperative fiducial model and postoperative fiducial model) were created by segmenting the fiducial markers from the preoperative and postoperative CT images reconstructed with the STANDARD filter. Segmentation was performed with automatic thresholding with a threshold range of 0–300 Hounsfield units. A 3D model of the femur (segmented femur model) was created by manually segmenting the bone in the preoperative CT image reconstructed with the BONE filter. A 3D model of the machined cavity (machined cavity model) was created by manually segmenting the machined cavity in the postoperative CT image reconstructed with the BONE filter (Fig. 5).

The four 3D models were created in two CT-based coordinate systems. Although the same CT scanner was used for preoperative and postoperative imaging, the same limb could not be placed identically between preoperative and postoperative scans. As such, the segmented femur model and the preoperative fiducial

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